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Takeshi Nishida

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EXAMINER

EOM, ROBERT J

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,155	Applicant(s) NISHIDA ET AL.	
	Examiner ROBERT EOM	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/21/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it is not limited to a single paragraph and is longer than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 14, line 3, it is unclear what a “measurement sample” is, it could be any sample that is “measurable”.

Regarding claims 14 and 15, both claims are directed towards “a measurement method for ulcerative colitis diagnosis and prognostic test”. There are no steps in either claim which describes to what acid degree will result in a positive diagnosis for ulcerative colitis, or how one can determine the prognosis for a patient who tests positive for ulcerative colitis.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 7, 8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petro et al. (US 2003/0080062 A1).

Petro discloses a measurement apparatus (Fig. 1) for ulcerative colitis diagnosis and prognostic test comprising: a solution mixing unit for mixing an eluent and a quinone solution (Fig. 1, see: 2nd dimension injector 2300), said eluent being supplied from a separation system including an eluent tank in which the eluent used for acid separation is stored (Fig. 1, see: mobile phase reservoirs 1100), at least one pump for sending the eluent (Fig. 1, see: pump 1200), a sample injection unit for injecting a sample into the eluent (Fig. 1, see: 1st dimension injector 1300), and an acid separation column for separating short-chain fatty acids included in the sample that is injected from the sample injection unit (Fig. 1, see: 1st dimension column 1500), and said quinone solution being supplied from a solution sending system including a solution tank (Fig. 1, see: solvent reservoir 2100) in which the quinone solution containing quinone and supporting electrolyte is stored, and at least one pump for sending the quinone solution (Fig. 1, see: pump 2200); and an acid degree measurement unit for measuring the acid degrees of the short-chain fatty acids included in a mixture solution that flows from the solution mixing unit; wherein said acid degree measurement unit continuously measures the acid degrees of the short-chain fatty acids included in the sample, which are successively mixed into the quinone solution by the solution mixing unit (Fig. 1, see: detector 2600).

Petro et al. discloses the claimed invention except for the use of quinone as a post column derivatization reactant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use quinone as a post column derivatization reactant, since it has been held to be within the general skill of a worker in

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the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Further, Statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art apparatus (or process). See, e.g., In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Regarding claims 7 and 8, modified Petro et al. discloses all of the claim limitations as set forth above, but the reference does not explicitly disclose the flow rate of the eluent to the acid separation column in 7.96 mm/min~60.2 mm/min, and the reference does not explicitly disclose the flow rate of the quinone solution is 891 mm/min~5102 mm/min. As the volume of eluent and quinone solution consumed and operational cost are variables that can be modified by adjusting the said flow rates, with said volume of eluent and quinone solution consumed and operational cost both increasing as the flow rates are increased, the precise flow rate would have been considered a result effective variable by one having ordinary skill in the art at the time

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the invention was made. As such, without showing unexpected results, the claimed flow rates cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the flow rates of the eluent and the quinone solution to obtain the desired volume of eluent and quinone solution consumed and operational cost (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 13, modified Petro et al. discloses all of the claim limitations as set forth above. Modified Petro et al. does not explicitly disclose the length of a flow path provided between the solution mixing unit and the acid degree measurement unit is 20 cm~80 cm. Since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the length of the flow path provided between the solution mixing unit and the acid degree measurement unit, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (dimension) is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

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8. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over modified Petro et al. (US 2003/0080062 A1), in view of Hayashi (USP 5,888,403).

Regarding claims 2 and 3, modified Petro et al. discloses all of the claim limitations as set forth above. Modified Petro et al. further discloses a solution mixing unit (Fig. 1, see: second-dimension injector)

Modified Petro et al. does not explicitly disclose the solution mixing unit includes a main tube in which the quinone solution flows, and a side tube in which the eluent flows, and said side tube penetrates into the main tube so that an aperture plane of a front end thereof is parallel to an inner diameter plane of the main tube. Additionally, modified Petro et al. does not explicitly disclose a cross-section area of the front end of the side tube is $\frac{1}{3}$ or lower relative to an inner cross-section area of the main tube.

Hayashi teaches a water treatment system comprising a ozone injecting/mixing section (Fig. 6) with an ozone injection tube (32) which penetrates the water portion of the cylinder member (80A) with a vane member (33) parallel to the inner diameter of the water portion of the cylindrical member. The cross-section area of the ozone injection tube being less than $\frac{1}{3}$ the cross section of the water portion of the cylinder member.

Petro et al. and Hayashi are analogous because both references are directed towards the injection mixing and treatment of aqueous solution.

It would have been obvious to one having ordinary skill in the art at the time of the invention to use the inline injector in the system of modified Petro et al., as taught by Hayashi, since doing so is a simple substitution of one known element for another to obtain predictable results.

9. Claims 4-6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over modified Petro et al. (US 2003/0080062 A1), in view of, Damjanovic (USP 5,011,608).

Regarding claim 4, modified Petro et al. discloses all of the claim limitations as set forth above.

Modified Petro et al. does not explicitly disclose the acid degree measurement unit including a working electrode in which electrochemical reaction of the quinone proceeds, a reference electrode serves as a basis for a voltage control of the working electrode, and a counter electrode that makes a pair with the working electrode to flow a current; and measuring a current of the quinone that flows through the working electrode in a state where a voltage is applied to the working electrode so that it has a constant voltage over the reference electrode.

Damjanovic teaches an HPLC-EDC system (Fig. 1), with an electrochemical detector (Fig. 1, see: ECD 22; Fig. 2) which comprises a working electrode (Fig. 2, see: 48), a reference electrode (Fig. 2, see: 52), and an auxiliary electrode (Fig. 2, see: 50).

Modified Petro et al. and Damjanovic are analogous because both references are directed towards HPLC based detection systems.

It would have been obvious to one having ordinary skill in the art at the time of the invention to use the EDC in the system of modified Petro et al., as taught by Damjanovic, since doing so provides for the detection of o-quinones (C27/L10-12), and therefore encompasses applying a known technique to a known device ready for improvement to yield predictable results.

Regarding claim 5, modified Petro et al. discloses all of the claim limitations as set forth above. Danjanovic further discloses the acid separation column is an ion exclusion type column for separating a target sample by a difference in electrostatic repulsive forces of ions having the same charge as an ion-exchange group (C16/L46).

Regarding claim 6, modified Petro et al. discloses all of the claim limitations as set forth above. Danjanovic further discloses a degasser for removing bubbles and dissolved oxygen included in the quinone solution and the eluent is provided in a flow path from the eluent tank and a flow path from the solution tank, respectively (C14/L47-48).

Regarding claim 9, modified Petro et al. discloses the claimed invention except for the eluent is a water solution containing 0.1 mM of perchloric acid. Modified Petro et al. does disclose the an aqueous based mobile phase (Danjanovic, C14/L43) and the use of the ECD requires a conductive mobile phase (Danjanovic, C27/L28-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a water solution containing 0.1 mM of perchloric acid, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

10. Claims 10 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over modified Petro et al. (US 2003/0080062 A1), in view of, Damjanovic (USP 5,011,608), in further view of, Takamura et al. (Determination of the free fatty acid content in fats and oils by flow injection analysis with electrochemical detection).

Regarding claims 10 and 12, modified Petro et al. discloses all of the claim limitations as set forth above.

Modified Petro et al. does not explicitly disclose the quinone solution being an ethanol solution containing 3mM~6mM of quinone and 50 mM~150mM of lithium perchlorate. Additionally, modified Petro et al. does not explicitly disclose the acid degree measurement unit enables measurement up to an acid measurement sensitivity of 5 μ M~2 μ M.

Takamura et al. teaches a system of determining the free fatty acid content with electrochemical detection, where the sample is dissolved in an ethanol solution containing 3mM VK₃, and 38 mM LiClO₄ (p980, see: procedure). Where the electrochemical detector (Fig. 1 (B)) has a 25 pmol detection limit (p982/C1.L10).

Modified Petro et al. and Takamura are analogous because both references are directed towards electrochemical detection systems and methods.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the quinone solution in the system of modified Petro et al., since it has been held to be within the general skill of a worker in the art selected to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *in re Leshin*, 125 USPQ 416. Further, Petro et al. discloses the claimed invention except for the concentration range of 50mM~150mM of lithium perchlorate. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to have a 50mM~150mM concentration of lithium perchlorate, since it has been held that where the general conditions of a claim are

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disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, USPQ 233.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over modified Petro et al. (US 2003/0080062 A1), in view of, Renom et al. (Simple gas chromatography analysis of faecal butyrate: application to patients at risk of pouchitis).

Regarding claim 11, modified Petro et al. discloses all of the claim limitations as set forth above.

Modified Petro et al. does not explicitly disclose the sample being human stool containing six kinds of short-chain fatty acids which are lactic acid, acetic acid, propionic acid, butyric acid, isovaleric acid, and valeric acid.

Renom et al. teaches a gas chromatography analysis of faecal sample which analyzed acetate, propionate, isobutyrate, butyrate, and isovalerate (Fig. 1).

Modified Petro et al. and Renom et al. are analogous because both references are directed towards chromatography methods and apparatus for the detection of polymers.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a stool sample in the system of modified Petro et al., since it has been held to be within the general skill of a worker in the art selected to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *in re Leshin*, 125 USPQ 416.

12. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petro et al. (US 2003/0080062 A1), in view of Rich, Jr. et al. (USP 4,242,097),

further in view of Takamura et al. (Determination of the free fatty acid content in fats and oils by flow injection analysis with electrochemical detection).

Regarding claim 14, Petro et al. discloses a measurement method and apparatus for ulcerative colitis diagnosis and prognostic test comprising: a separation step of injecting a measurement sample into an eluent (Fig. 1, see: 1st dimension injector 1300) that flows into a separation column at a constant flow rate (Fig. 1, see 1st dimension column 1500); a solution mixing step of mixing the eluent that is sent from the separation column into a solvent that is sent at a constant flow rate (Fig. 1, see: 2nd dimension injector 2300); and a measurement step of continuously measuring the components of the resulting mixture (Fig. 1, see: detector 2600).

Petro et al. does not explicitly disclose the separation column being an acid separation column which separates short-chain fatty acids. Additionally, Petro et al. does not explicitly disclose the measurement step measuring the acid degrees of the short-chain fatty acids.

Rich et al. teaches a method and apparatus for the quantitative analysis of weakly ionized carboxylates (Abstract) which are separates the sample into components through an ion exclusion chromatography column (Fig. 1, see: 10), and measures the signal response through a conductivity meter (Fig. 1, see: 22) of various short-chain fatty acids (Fig. 2 and Fig. 3).

Petro et al. and Rich et al. are analogous because both reference are directed towards liquid chromatography methods and apparatuses.

It would have been obvious to one having ordinary skill in the art at the time of the invention to use an ion exclusion column in the method and apparatus of modified Petro et al., as taught by Rich, Jr. et al., since doing so amounts to a simple substitution of one known element for another to obtain predictable results.

Modified Petro et al. disclose all of the claim limitations as set forth above.

Modified Petro et al. does not explicitly disclose the derivatization solution being a quinone solution that contains quinone and supporting electrolyte and the acid degree measurement step measuring the mixture resultant which is produced by the measurement sample, being successively mixed into the quinone solution.

Takamura et al. teaches a method and apparatus for the determination of free fatty acids with electrochemical detection, where the sample is dissolved in a ethanol solution containing quinone and lithium perchlorate (p980/C1, see: Procedure).

Modified Petro et al. and Takamura et al. are analogous because both references are directed towards electrochemical detection of fatty acids.

It would have been obvious to one having ordinary skill in the art at the time of the invention to use the quinone solution of modified Petro et al., as taught by Takamura et al., since doing so enhances the detection sensitivity and reproducibility (p982/C1/L10).

Regarding claim 15, modified Petro et al. disclose all of the claim limitations as set forth above. Petro et al further discloses the solution mixing step comprising: forming a flow path by mixing a flow in a side tube which comprises the eluent flow, into a flow in a main tube which comprises the quinone solution flow; and discharging the eluent that

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flows from the side tube in parallel to the quinone solution that flows in the main tube, thereby to evenly diffuse the eluent into the quinone solution (Fig. 2).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT EOM whose telephone number is (571)270-7075. The examiner can normally be reached on Mon.-Thur., 9:00am-5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/
Primary Examiner, Art Unit 1797

/R. E./
Examiner, Art Unit 1797

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